## REMARKS

Claims 1, 5, 6, 8, 11 and 15–20 are pending in the application. Claims 1, 5, 6, 8, 11 and 15–20 have been amended.

In the office action dated September 3, 2008, the Examiner rejected Claims 1, 5, 6, 8, 11 and 15 - 20 under 35 USC 103(a) "as being unpatentable over Runnells et al. (US 3,752,145) in view of Niehoff (US 5,662,612)." Specifically, the Examiner asserted that:

> Runnells teaches a method of operating an injector detailed at Col 3: 'A tube is then attached to the outlet 22 of the syringe and the free end of the tube is submerged in contrast solution. Air is bled from the syringe by advancing the piston plate 14 toward the outlet 22. Additional contrast solution may then be drawn through the tube into the syringe housing by retracting the piston plate.' Runnells does not disclose sensing the syringe and automatically advancing the piston of the injector.
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> Niehoff discloses a power injector which automatically senses the presence and capacity of a syringe and advances and retracts the plunger automatically (see Abstract). Niehoff also teaches preprogramming the injection volume and syringe volume (see Col 9 line 38, Col 11 line 49, Col 12 line 5, and Fig 7E). As to claim 6, see Niehoff Fig 1a and Col 1, last paragraph.
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> Niehoff teaches that manually advancing and controlling the plunger is 'tedious and inefficient, not only because of the time consumed, but also because the operator must press and hold manual movement switches to produce the movement, and thus is physically tied to the injector and cannot use this time to make other preparations' It is well known that both the syringe and the tubing must be primed to remove air (Runnells) and that a syringe pump can be programmed to automatically advance to engage a plunger and to move the plunger forward and backward to load or prime the syringe (Niehoff). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the automated power injector of Niehoff with the loading and priming method of Runnells in order to reduce human error and accurately sense the syringe and plunger position in a loaded syringe (Niehoff abstract).
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> As to claims 18-20, Niehoff teaches adjusting the programmed parameters after mounting the syringe (Fig 6a).

With respect to Applicants" arguments set forth in the Amendment filed August 7, 2008, the Examiner further asserted that:

> Applicant's arguments filed 7 August 2008 have been fully considered but they are not persuasive. Applicant has argued that the combination does not automatically advancing the piston to prime the tubing without user input or

control. See rationale above the Niehoff teaches the advantages of automating the syringe loading procedure and Runnells teaches the importance of priming both the tubing and the syringe. The rejection is maintained as modified above. Furthermore, applicant's invention now claims operator input of the programmed volume, so arguments relating to the claims requiring all steps to take place automatically or without user input are not persuasive.

It is well established that, in determining obviousness, one must determine the scope and content of the prior art and ascertain the differences between the prior art and the claims at issue. *Graham v. John Deere* 383 U.S. 1, 17-18, 86 S. Ct. 684, 15 L. Ed. 2d 545, (1966). Further, the prior art reference or combination of references must teach or suggest all of the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496, (CCPA 1970). Applicants respectfully assert that the Examiner has ignored the requirement of establishing that all the elements of the claimed invention are set forth in the prior art, and has failed to assert a *prima facie* case of obviousness.

As admitted by the Examiner, Runnells does not disclose sensing the syringe and automatically advancing the piston of the injector. Indeed, contrary to the present invention, all procedures set forth in Runnells are executed manually. Nonetheless, the Examiner assert erroneously that Runnells and Niehoff can be combined to render the present invention obviousness because "Niehoff teaches the advantages of automating the syringe loading procedure and Runnells teaches the importance of priming both the tubing and the syringe."

Contrary to the Examiner's assertion, Niehoff does not disclose or suggest "automation" of syringe loading or any other activities for preparation for an injection procedure requiring injector piston/syringe plunger movement (that is, advancement or retraction). In that regard, injector piston/syringe plunger motion during preparation for an injection procedure in the case of Niehoff requires operator/manual activation of a control switch/button. As indicated by the Examiner, Niehoff discloses that it is tedious to require an operator to press and hold a manual movement switch to produce movement, and requires the operator to be "physically tied to the injector." Col. 2, lines 60-65. The solution provided by Niehoff is a locked mode for the plunger drive controller of the injector of Niehoff in which motion must be manually initiated by the activation of a manual switch by the operator. However, once the locked mode is

activated, plunger drive motion will be continued, "whether or not the operator continues pressing the switch," until the plunger drive reaches its fully-advanced or fully retracted position. See, for example, col. 2, line 66 to col. 3, line 8. A position encoder is provided to determine plunger position in the injector of Niehoff.

Applicants have amended the independent claims to even more clearly set forth that, contrary to Niehoff, advancement and/or retraction of the injector piston of the present invention is automatically initiated (that is, without manual/operator activation or intervention) to effect one or more actions of the methods for preparing for an injection procedure of the present invention. Niehoff does not disclose or suggest such automatic initiation of injector piston/syringe plunger motion.

With respect to independent claim 1, Niehoff does not disclose or suggest *inter alia*: (1) providing data of a fluid volume of a fluid path comprising a syringe and tubing in fluid connection with the syringe to an injector; (2) automatically initiating advancing of the piston of the injector to engage the plunger of the syringe (in response to sensing the mounted syringe) and advancing of the plunger to the distal end thereof to expel air from the fluid path; (3) retracting the piston based on the fluid volume to retract the plunger and aspirate fluid into the fluid path; and (4) automatically initiating advancing, without operator input, of the piston to prime the fluid path.

With respect to independent claim 8, Niehoff does not disclose or suggest *inter alia*: (1) providing data of a predetermined fluid volume to an injector; (2) automatically initiating advancing of the piston of the injector to engage the plunger of the syringe in response to sensing the syringe, (3) automatically initiating advancing of the piston of the injector to advance the plunger to the distal end of the syringe if the syringe is an empty syringe; and (4) automatically initiating retracting of the piston a determined distance based on the predetermined fluid volume to retract the plunger and aspirate fluid into the syringe if the syringe is an empty syringe; wherein the automatically advancing and retracting of the piston is without operator input.

With respect to independent claim 11, Niehoff does not disclose or suggest *inter alia*: (1) providing data of a predetermined fluid volume to an injector; and (2) automatically initiating advancing, without operator input, of the piston a distance determined by the injector to prime the syringe and a tube connected to the syringe,

wherein the distance the piston is advanced for priming is based on a fluid volume of the tube.

The substantial benefits of the various "auto features" of the present invention such as "auto engage", "auto fill", "auto prime" and "auto retract" in which motion of the injector piston/syringe plunger is automatically initiated (that is, initiated without operator/manual intervention) are set forth in the specification and have been discussed in previous filed amendment.

Once again, motion of the injector piston, and thereby motion of the syringe plunger, of Niehoff is not initiated without operator/manual intervention or activation during injection procedure preparation activities. For example, air removal from the syringe of Niehoff clearly must be effected manually. As set forth in Figure 6B, the operator is queried "Have you evacuated all air from the XXX ml syringe and tubing?" (Emphasis added). See also, Col. 12, lines 36-44.

The Examiner cannot ignore the above-identified express claim limitations distinguishing the present invention from the disclosures of Runnels and/or Niehoff. See Ex Parte Murphy and Burford, 217 USPQ 479, 481 (P.O. Bd. Appls. 1982) ("it is error to ignore specific limitations distinguishing over the cited reference"); In re Boe, 505 F.2d 1297, 184 USPQ 38 (CCPA). Further, given the total lack of any disclosure or suggestion of automatic initiation of injection piston/syringe plunger movement during preparation for an injection procedure in either Runnels or Niehoff, Applicants respectfully assert that the Examiner is impermissibly using the disclosure of the present invention as a guide in modifying the teachings of Runnels and/or Niehoff. See Orthopedic Equipment Co., Inc. v. United States, 702 F. 2d 1005, 1012, 217 USPQ 193, 199 (Fed. Cir. 1983):

In view of the above amendments and remarks, the Applicants respectfully requests that the Examiner, indicate the allowability of the Claims, and arrange for an official Notice of Allowance to be issued in due course.

Respectfully submitted,

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